Quinz Global Law School
Life Sciences, R&D and the Law

Closed Workshop Consortium Agreements for R&D Projects in the Life Sciences Sector 3 May 2013

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Negotiating consortium agreements is often a challenging endeavour. The common interests and objectives in setting up a successful R&D collaboration in a cutting edge research area are generally clear. However, due to the variety of negotiating partners with different interests, objectives and prior commitments, intellectual property (IP) ownership, access rights, IP valuation, project management, liability and post project issues tend to remain considerable hurdles.

These hurdles were discussed at the KU Leuven on 3 May 2013 during the workshop Consortium Agreements for R&D Projects in the Life Sciences Sector' which was organized as part of the Quinz Global Law School. The debate was initiated by an expert panel consisting of top level representatives from the pharmaceutical industry, academia, biotech companies, technology transfer offices (TTOs) and contract research organizations. This report seeks to provide a summary of the constructive discussion, some conclusions and a number of solutions for issues which are currently experienced in industry. The main topics covered by the workshop are the benefits to enter into publicly funded consortia, the challenges in establishing a consortium, issues relating background and foreground IP and in particular co-ownership, the specific nature of universities in consortia and the issue of publication.

The panel consisted of: Inge Basteleurs (General Counsel Biocartis), Daphné Derouane (Senior patent counsel UCB), Michel Detheux (Co-founder & CEO iTEOS Therapeutics), Bruno Lambrecht (Head Legal Department LRD), Vincent Lannoy (Euroscreen), Olivier Lescroart (LRD), Bart Lintermans (Partner at Quinz), Kevin Nachtrab (President of the Licensing Executives Society International and Senior IP Attorney at Johnson & Johnson), Sean O'Connor (Professor University of Washington School of Law), Magali Pinot (Legal Manager IMI), Ilse Samoy (Professor Institute for the Law of Obligations, KU Leuven), Annie Van Broeckhoven (CEO Q-Biologicals), An Van Den Broecke (Innovation Manager TTO UGent), Esther Van Zimmeren (Post-doctoral Researcher Centre for Intellectual Property Rights (CIR)), Christophe Verbruggen (Director Legal Affairs, Jansen Pharmaceutica) and Pieter Wyckmans (Partner at Quinz, moderator).

1. *Benefits to enter into publicly funded consortia*

There are many benefits in establishing publicly funded consortia. These benefits mainly relate to funding, risk sharing, access to new knowledge and networking opportunities. For *large companies*, attracting public funding is especially important to be able to engage in innovative research and to set up risky research projects. For *academia*, attracting public funding is also the most important aspect. Attracting public funding is not the most important reason for *Small and Medium-sized Enterprises (SMEs)* to collaborate in publicly funded consortia, as normally only 75% of the research

costs are covered, which may cause great budgetary challenges for SMEs. All parties value the networking aspects and the concentration of specific knowledge, know-how and expertise in the consortium.

2. *The Challenges in establishing a (publicly funded) consortium*

The greatest challenge in establishing a consortium is finding your way through the maze of funding schemes, which exist in Flanders and at the EU level. Special knowledge and expertise is often required to understand and correctly use the schemes. Furthermore, every funding scheme has its own specifics, including its own rules related to IP, such as access to background IP, use rights, membership, termination possibilities, *etc.*

It can therefore be hard to identify the most appropriate funding scheme for a certain research project. Often, not all participants to a publicly funded consortium are aware of the consequences related to a particular type of collaboration. This can result in different expectations between participants. It is considered important to actively and consciously manage the expectations of the parties in consortium agreements. Clear communication of the expectations by all the parties involved is therefore absolutely necessary.

For large companies the question regarding the source of the funding seems to be less important. They have the necessary expertise to understand the funding schemes in-house and they focus on the beneficial and innovative results of the research and the desired output of the research. For instance whether it will be basic chemistry or a final product in deciding on the type of funding and the need for further collaboration. *SMEs*, and in particular start-up companies in the life sciences that are involved in clinical trials, are generally more concerned about getting to a stable source of funding, as this will enable them to carry out the various stages of the clinical trials.

In the *United States* there has been a discussion on the type of research that should be carried out with public funding. Public funding is usually intended for early stage research where the outcome will then become a 'public good'. When the research is closer to the commercial stage, parties will rather use corporate sponsored consortium agreements and will consider public funding only as a last resort.

3. *Ownership Foreground IP*

In private consortium agreements funded by industry participants, the question arises whether the IP ownership should vest with the party that generates the foreground IP or with the party that funds the project. However, not all negotiations concerning foreground IP are dominated by ownership issues. Several panel members argue that participants are often unable to explain why they need full ownership of the foreground IP. Therefore, it is essential that in preparation of the negotiations one considers whether exclusive ownership is required in order to accomplish the objectives of the consortium and their goals in the exploitation phase. Exclusive ownership is not always necessary to benefit from the foreground IP. However, every party wants some form of compensation for their efforts in the consortium.

Most consortia in the life sciences are nowadays *precompetitive*. In early stage projects, access to high-level expertise and infrastructure, freedom to operate, exclusivity and a right of first offer or a right of first refusal may be equally important as ownership of the results and the associated foreground IP. The added value of the consortium is not mainly related to IP ownership, but in the access to and use of the foreground IP from which competitors are excluded. *Large pharmaceutical* companies increasingly require exclusivity, *e.g.* on a molecule, rather than IP ownership, because they want to circumvent the fiduciary duties that correspond with ownership. As a result of these changing preferences, in a collaboration between industry and academia, it becomes more common for the generators (usually universities) to obtain ownership of foreground IP. If the objective of the research is not precompetitive, but focused on an end-product , industry partners will generally be reluctant to conduct the research within the framework of a consortium. In case parties will attempt to set up a consortium anyway, the negotiations on the consortium agreement about IP ownership will become much harder. In the United States, the tax exempt status of most universities prohibit them from pre-assigning any inventions developed under sponsored research or consortium agreements, especially when work is to be done in tax exempt bond financed facilities. Likewise, universities generally cannot precommit to an exclusive license to the private consortia members either, for the same reasons. Finally, if any federal public funding is involved in the research, then the Bayh-Dole Act governs the disposition of inventions.

4. Co-ownership

For *industry*, co-ownership of IP is often *difficult to manage*, certainly when the IP would be related to an end product. Moreover, co-ownership creates a complex legal environment with respect to a variety of legal domains such as tax law, IP law, bankruptcy law and competition law. With respect to co-owned IP, the rules regarding exploitation and licensing may differ from country to country and sometimes different regimes exist with respect to copyright and patent law. In some countries exploitation or the grant of an (exclusive) license are only possible after the consent of the co-owners. This may seriously delay or even block further commercialization of the innovations. An alternative to co-ownership would be to establish a joint-venture, which would obtain ownership of the IP and give grant back licenses to the parties. However, the establishment of a joint-venture requires more formalities than 'simple' co-ownership of the IP and the joint-venture should preferably remain relatively small in order to be manageable.

For *academia*, however, co-ownership is a relatively common solution. Universities strive to have fair co-ownership agreements. There are no clear-cut rules of what would constitute a fair agreement: fairness can only be assessed on a case-by-case basis. The comments about ownership of university developed IP in Section 4 above, apply equally in the co-ownership situation.

5. Background IP

Granting access to background IP is an essential part of each consortium agreement: without such (mutual) access, the cooperation serves no purpose. The terms of such access agreements are either determined by funding schemes imposed by public authorities or, in the absence thereof, by the

parties themselves during the negotiations. In this area, there is a strong need for legal certainty, because use of foreground IP might infringe background IP or third parties' rights, hence impeding the research within the framework of the consortium.

There are two ways of ensuring legal certainty: either by negotiating a negative list of background IP which is *not* to be used, or by providing a positive list which includes all background IP that *can* be used. The parties will determine which kind of list is most suitable for a given agreement. *E.g*. some parties prefer a negative list when their IP has particular commercial value, so that they can indicate clearly which assets are beyond the scope of the consortium agreement.

6. Specific nature of universities

A specific characteristic of universities is their non-hierarchical structure based on the notion of academic freedom. Unlike companies which have a scientific officer who determines the research strategy, universities do not have *one* widely-supported research strategy, but a variety of bottom up initiatives. It is essential for universities to limit the obligations created by way of a research collaboration agreement to the specific department involved in and benefiting from the agreement, for instance with respect to access and use of background IP.

The industry representatives recognize the importance of this specific characteristic but stress the need for legal certainty and freedom to operate. They tend to expect a high degree of professionalism and organization from universities. It should, for instance be avoided at all times that another research group of the same university would acquire a blocking patent.

The university representatives acknowledge the need for legal certainty and freedom to operate and argue that the best guarantee they can offer is 'internal hygiene'. An effective *TTO* should have a central and good overview of the university's IP portfolio. Such internal hygiene would avoid problems of freedom to operate caused by other departments from the same university. Moreover, researchers who receive external funding from a private or public source have a responsibility not to disclose information they get from their commercial partners. Academic freedom can never serve as a valid justification for leaking confidential information. Corporate sponsored research necessarily entails a certain limitation of academic freedom.

In the *United States*, the assignment of IP to commercial partners is controversial. Universities tend to require a reservation of rights for research use for other researchers across the university and sometimes even for all US universities when rights are transferred to a company. Another problem is that state universities are not willing to waive their sovereign immunity, which renders it difficult to take action in case they are involved in IP infringements even though the same state universities have started infringement procedures against private actors.[1] A body of case-law is evolving in this area and has received a lot of attention.

[1] Note that once a state university initiates IP litigation against a private actor, it has waived sovereign immunity with regard to any IP infringement counterclaims by that defendant.

7. Publication

The issue of publication is not new, but continues to raise some challenges in the management of consortia because of the different interests which are at stake. Whereas companies are looking for ways to monetize the outcome of the research by applying for *patents*, the priority for universities is still for valorisation in the form of *publications* even though universities increasingly apply for patents themselves as well. For industry, the problem is that publications end up in the public domain and create prior art which may limit or even render it impossible to get a patent with respect to the related inventions. However, for academia, it is important to have scientific priority*, i.e.* to be the first one to publish the research results in a peer-reviewed journal with a high impact factor. This variety of interests requires good communication between the consortium partners and careful management of the timing of the publications and patent applications.

It is self-evident that these issues need to be addressed in a dedicated clause in the consortium agreement. Generally, such publication clauses no longer pose significant problems. It is generally accepted that parties agree on a 'reasonable' delay of publications in order to provide industry partners with a realistic timeframe to obtain a patent. However, in practice it is often unclear what reasonable means. Companies generally push for a longer period, ranging from three months (which is an absolute minimum for most companies to draft a decent patent application) to a year (which is considered to be the maximum for universities).

In addition, some companies try to impose a review period, because they want to retain some oversight of what is being published (although some professors might object to this, because they disfavour commercialisation of university research). The review period should be kept short (*e.g.* one or two months) and it should be clear that in the absence of any objections or remarks publication should not be delayed any further and can be pursued. For instance, a company might want to exclude certain information from the publication when that information is considered confidential and not disclosed in the patent application. *TTOs* will often protest against withholding such information because it would violate academic freedom. Therefore, it is key for companies to identify early on what they consider confidential business information and to collaborate with scientists that have some understanding of the importance of IP and know-how and are willing to accept a certain limitation of their academic freedom in exchange for the benefit of a fruitful, potentially long-term collaboration with their commercial partners.